

REMARKS

Claim Amendment:

Claim 32 has been amended to clarify the claim. Specifically, the claim had previously been amended to reflect that Cdn-1Δ1 was represented by SEQ ID NO:22. However, it has come to the undersigned agent's attention that SEQ ID NO:22 is nearly duplicative of SEQ ID NO:7 (with the exception of a single amino acid omission, discussed below). SEQ ID NO:22 is identified in the specification with reference to Figure 11, which illustrates the sequences for Cdn-1Δ1, Cdn-1Δ2 and Cdn-1Δ3. However, each of these variants is a truncated version of the full-length Cdn-1 as shown in Figure 11 (taking into account one error in the sequence depicted in the figure, discussed below) and as described in the specification (see page 4, lines 20-23 and page 27, lines 1-3), wherein the remainder of the protein sequence after truncation is stated to be identical to Cdn-1. Therefore, Figure 11 is described as showing the full-length Cdn-1 sequence with arrows indicating the positions of the truncation for each of the variants. As such, Applicants have amended Claim 32 to more clearly recite, as shown in Figure 11 and described in the specification, that Cdn1Δ1 corresponds to positions 60-211 of SEQ ID NO:7 (Cdn-1) (see page 4, lines 20-23 and page 27, lines 1-3 for support). Applicants submit that this amendment does not add new matter, nor does it raise an issue for further consideration, since the Examiner has already performed a search and examination with regard to Cdn-1. O/K

Applicants' agent has further noted that Figure 11 does contain one obvious error (referenced above), which is an omission of the isoleucine residue at position 123, as can be ascertained from comparison of the sequence in Figure 11 to the Cdn-1 sequence in SEQ ID NO:7 (Fig. 3). Otherwise, SEQ ID NO:7 and SEQ ID NO:22 are identical. Applicants also submit herewith a proposed correction to Figure 11 for the Examiner's consideration, with the correction marked in red ink (an addition of "I" representing isoleucine at the appropriate position), to correct the typographical error in the drawing. Assuming that the proposed correction is accepted, Applicants have amended the specification so that Figure 11 refers to SEQ ID NO:7 instead of SEQ ID NO:22, which amendment is supported by the specification as discussed above. This amendment should obviate any need to make changes to the Sequence Listing, since all reference to SEQ ID NO:22 has been removed from the specification. D/K

Restriction Requirement:

Applicants note that the Examiner has maintained the finality of the prior Restriction Requirement. However, as noted in the response to Restriction Requirement, if the elected claims of Group I are found allowable, Applicants reserve their right to amend the claims of Group II, if necessary, to be commensurate in scope with the product claims of Group I, and to request that such amended claims that depend from or otherwise include all the limitations of the allowable product be rejoined and examined for patentability. In re Brouwer, 37 USPQ2d 1663 (Fed. Cir. 1996); In re Ochiai, 37 USPQ2d 1127 (Fed. Cir. 1995). Therefore, Claims 33-38 and 64-65 have not been canceled.

Information Disclosure Statement:

The Examiner has noted that copies of the references from the parent applications can not be located and has requested that Applicants send copies of the references as a courtesy. Unfortunately, Applicants' current attorneys and agents were not the original representatives for this series of applications, and copies of the references are not readily available in the undersigned agent's office. It is further noted that the list of references submitted in the 1449 is quite large. However, Applicants do wish to have all references of record considered, and so the Examiner is respectfully requested to notify Applicants' agent by telephone if the parent file references can not be located at the time the Examiner reviews this response. In that event, Applicants will attempt to obtain copies of all of the references so that they can be considered.

Rejection of Claim 60 Under 35 U.S.C. § 112, Second Paragraph:

The Examiner has rejected Claim 60 as being improper because it is dependent on a rejected claim. Applicants submit that this rejection is believed to be moot pending the withdrawal of the rejection of Claims 32 and 59-63 under 35 U.S.C. § 102(e).

Rejection of Claims 32 and 59-63 under 35 U.S.C. § 102(e):

The Examiner has rejected Claims 32 and 59-63 under 35 U.S.C. § 102(e), contending that these claims are anticipated by U.S. Patent No. 5,672,686 to Chittenden. The Examiner contends

that the '686 patent discloses a sequence of Bcl-Y which allegedly shares high homology with SEQ ID NOs:9, 21 and 22. The Examiner contends that the '686 patent discloses polyclonal and monoclonal antibodies that bind to Bcl-Y and that while the sequences in the instant application are not identical to the sequence of the Bcl-Y protein, antibodies that bind to Bcl-Y would be expected to bind to the claimed sequences of SEQ ID NOs:9, 21 and 22.

Applicants traverse the rejection of Claims 32 and 59-63 under 35 U.S.C. § 102(e).

First, Applicants submit that on the face, U.S. Patent No. 5,672,686 does not appear to be effective as prior art against the present application. The present application is a divisional of U.S. Application Serial No. 08/320,157, filed October 7, 1994, which discloses SEQ ID NO:7 (Cdn-1), SEQ ID NO:9 (Cdn-2), SEQ ID NO:21 (Cdn-3) and positions 60-211 of SEQ ID NO:7 (Cdn-1Δ1; see remarks above with regard to SEQ ID NO:22). The filing date of the '157 parent application is four days prior to the filing date of the '686 patent and therefore, the disclosure in the instant specification predates the disclosure in the '686 patent. The '686 patent is a *continuation-in-part* of its priority application, and the Examiner has not provided any discussion regarding the disclosure of the '686 priority document.

Moreover, even *if* the priority document to the '686 patent contains a disclosure of the Bcl-Y protein and antibodies thereto, Applicants submit that the '686 patent is not effective prior art for the following reason.

The present application claims priority to U.S. Application Serial No. 08/160,067, filed November 30, 1993, which predates the earliest priority filing date of the '686 patent by several months. The '067 application discloses the nucleic acid and amino acid sequence for Cdn-1 (referred to as Cdi-1 in the '067 application), as well variants and modified forms of Cdn-1 and antibodies that bind to Cdn-1.

The Examiner has rejected the claims directed to an antibody that binds to Cdn-2, Cdn-3 or Cdn-1Δ1 on the basis that an antibody that binds to Bcl-Y would allegedly bind to any of these Cdn proteins due to the high level of homology between the proteins. It is noted that antibodies that bind to Cdn-1 (SEQ ID NO:7) have been deemed to be free of the prior art. In support of the rejection, the Examiner provides alignments which indicate that the amino acid sequence for Bcl-Y is 97.3% identical to SEQ ID NO:9 (Cdn-2), 33.2% identical to SEQ ID NO:21 (Cdn-3), and 98.6% identical

to SEQ ID NO:22 (Cdn-1Δ1). As discussed above with regard to the claim amendment, SEQ ID NO:22 is nearly identical to SEQ ID NO:7 and therefore, since the Bcl-Y does contain the isoleucine 123 that was inadvertently omitted from SEQ ID NO:22, Bcl-Y should be more than 98.6% identical to SEQ ID NO:7 (Cdn-1). Furthermore, the present specification teaches that SEQ ID NO:7 is about 97% identical to SEQ ID NO:9 (Cdn-2) (see page 24, lines 27-29), which is very similar to the identity between Bcl-Y and SEQ ID NO:9 provided by the Examiner. Therefore, one can conclude that Bcl-Y and Cdn-1 are most similar to one another, have nearly the same identity to SEQ ID NO:9 (Cdn-2), and have apparently the same identity to SEQ ID NO:21 (Cdn-3) (noting the differences between Bcl-Y and Cdn-1 and the alignment between Bcl-Y and Cdn-3 provided by the Examiner). Obviously, Cdn-1Δ1 (positions 60-211 of SEQ ID NO:7) is more identical to Cdn-1 than to Bcl-Y.

In making the rejection under § 102(e) in view of the '686 patent, the Examiner is equating an antibody that binds to Bcl-Y with an antibody that binds to any of SEQ ID NO:9, SEQ ID NO:21 or SEQ ID NO:22 (i.e., SEQ ID NO:7). As discussed above, Cdn-1 is substantially as similar as Bcl-Y, or more similar than Bcl-Y, to the rejected sequences. Therefore, referring to the Examiner's argument, one can therefore conclude that antibodies against Cdn-1 should also be equated with antibodies that bind to any of SEQ ID NO:9, SEQ ID NO:21 or SEQ ID NO:22 (SEQ ID NO:7). Also as discussed above, the present application priority document, filed November 30, 1993, teaches antibodies that bind to Cdn-1. Therefore, the earliest priority document for the present invention (i.e., U.S. Application Serial No. 08/160,067) logically provides a disclosure sufficient to retain the benefit of priority for the claimed invention, and the '686 patent is not effective prior art against the claimed invention.

In view of the foregoing discussion, Applicants respectfully request that the Examiner withdraw the rejection of Claims 32 and 59-63 under 35 U.S.C. § 102(e).

Applicants have attempted to address all of the remaining issues set forth in the February 13 Office Action and submit that the claims are in a condition for allowance. In the event that the Examiner has any questions regarding Applicants' position, the Examiner is encouraged to contact the below-named agent at (303) 863-9700.

Respectfully submitted,

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Marked Version Showing Amendments

In the Specification:

On page 4, the paragraph spanning lines 20-23 has been amended as shown below:

Figure 11 depicts the cdn-1 (SEQ ID NO:7) derivative proteins $\Delta 1$ (positions 60-211 of SEQ ID NO:7), $\Delta 2$ (positions 71-211 of SEQ ID NO:7) and $\Delta 3$ [(SEQ ID NO:22)] (positions 96-211 of SEQ ID NO:7). The N-terminal residues are indicated by the arrows. The remainder of the derivative proteins is the same as full-length cdn-1.

In the Claims:

Claim 32 has been amended as shown below.

32. (Twice Amended) A composition comprising a monoclonal or polyclonal antibody which specifically binds to a CDN protein selected from the group consisting of: CDN-1 comprising the amino acid sequence of SEQ ID NO:7, CDN-2 comprising the amino acid sequence of SEQ ID NO:9, CDN-3 comprising the amino acid sequence of SEQ ID NO:21 and CDN-1 $\Delta 1$ comprising the amino acid sequence of [SEQ ID NO:22] positions 60-211 of SEQ ID NO:7.